

DEC - 4 2000

K662749

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510(k) Summary

Endoscope Contour Detection Device 3DX45

XCF-Q140L/13D Colonovideoscope

A. Submitter's Name, Address, Phone and Fax Numbers

1. Manufacturer of the Subject Devices

Name and address of manufacturer: Olympus Optical Co., Ltd.
2-3-1 Shinjyuku Monolis Nishishinjyuku
Shinjuku-ku, Tokyo, Japan
Registration: 8010047
Address, Phone and fax numbers 2951 Ishikawa-Cho,
Of R&D Department, Hachioji-shi, Tokyo 192-8507
Endoscope Division Japan
Telephone (426) 42-5177
Facsimile (426) 46-5613

B. Name of Contact Person

Name: Laura Storms-Tyler
Address, Phone/fax numbers: Olympus America Inc.
Director, Regulatory affairs
Two Corporate Center Drive
Melville, NY 11747-3157
Telephone (631) 844-5688
Facsimile (631) 844-5554

C. Device Name, Common Name, Classification Name and Predicate Devices

Device Name: Endoscope Contour Detection Device 3DX45
Colonovideoscope XCF-Q140L/13D

Common Name: Endoscope Contour Detection Device
Colonoscope

Predicate Device:

Model	Name	510(k) number
Image Jet	Spatial Imaging Sensor for Endoscopy	K970782
CF-Q160AL/I	Colonovideoscope	K001241

D. Description of the Device(s)

The Endoscope Contour Detection Device 3DX45 has been designed for the display of the spatial image of an endoscope. This system consists of the system controller unit, probe, external marker, reference plate, water resistant cap L, water resistant cap S, probe cable, marker cable, LCD cable, ten-key pad, and power cord. Please refer to Instruction Manual.

The probe with the built-in 12 source coils is inserted from the forceps entrance into the endoscope, and the reference plate with built-in three source coils is put on the body of the patient, and the external marker with built-in one source coil is put on the body of the patient. The source coils in the probe, reference plate, and the external marker generates the magnetic fields driven by the alternating current of a different frequency respectively. The sense coils detect the generated magnetic fields as current signals. The detected current signals are converted into the position data of each source coil in the probe, the reference plate and the external marker by calculation. The obtained position data is converted into the shape of the insertion section of the endoscope and is displayed on the monitor. The probe is designed to be used in the biopsy channel of flexible endoscopes having a biopsy channel of ϕ 3.2 mm or larger in diameter. The user also has the option of using a dedicated endoscope with built-in coils, so that the XB01-657-6 probe is not required. The XCF-Q140L/I3D colonovideoscope is a variable stiffness colonoscope that has the magnetic coils built into endoscope.

E. Intended Use of the Device

The Endoscope Contour Detection Device 3DX45 and the XCF-Q140L/I3D colonovideoscope have been designed for the detection and display of the spatial image of an endoscope.

F. Summary including Conclusions drawn from Non-clinical tests

When compared to the similar device, the Endoscope Contour Detection Device 3DX45 and the XCF-Q140L/I3D colonovideoscope do not incorporate any significant changes in intended use, method of operation, material or design that could affect the safety or efficacy of this device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC - 4 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America, Inc.
Two Corporate Center Drive
MELVILLE NY 11747-3157

Re: K002749
Olympus Endoscope Contour Detection Device 3DX45
and colonoscope, XCF-Q140L/I3D
Dated: August 25, 2000
Received: September 5, 2000
Regulatory Class: II
21 CFR §876.1500/Procode: 78 FDF
21 CFR §892.1600/Procode: 78 JAB

Dear Ms. Storms-Tyler:

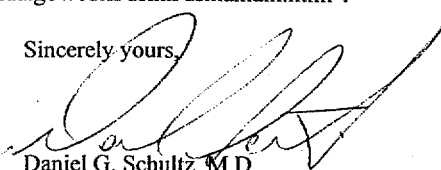
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002749

Device Name: Endoscope Contour Detection Device 3DX45
And the associated colonoscope, the XCF-Q140L/13D

Indications for Use:

The Endoscope Contour Detection Device 3DX45 and the XCF-Q140L/13D colonovideoscope have been designed for the detection and display of the spatial image of an endoscope.

(Please do not write below this line. Continue on another page is needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

David A. Sepman
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K002749